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Award Number: **W81XWH-06-1-0180**

TITLE: **ProCEED Pilot Study (Prostate Cancer Study of Ethnicity, Exercise and Diet)**

PRINCIPAL INVESTIGATOR: **Katrine L. Wallace**

CONTRACTING ORGANIZATION:
University of Illinois at Chicago
Chicago, IL 60612-7205

REPORT DATE: **DECEMBER 2008**

TYPE OF REPORT: **ANNUAL** Summary

PREPARED FOR: **U.S. Army Medical Research and Materiel Command**
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
12-29-2008	Annual Summary	30 NOV 2007 - 29 NOV 2008

4. TITLE AND SUBTITLE
ProCEED Pilot Study
E

(Prostate Cancer Study of Ethnicity, Exercise and Diet)

5a. CONTRACT NUMBER
W81XWH-06-1-0180

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Katrine L Wallace, MA
Sylvia E. Furner, MPH, PhD
Vincent L. Freeman, MD, MPH

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Illinois Chicago
809 S Marshfield Avenue, Rm 608
MC 551
Chicago, IL 60612-7205

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
and
Fort Detrick, MD 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The third year of the grant was dedicated to continued subject enrollment. At the end of the enrollment period there were 87 subjects enrolled into the study (57 prostate cancer cases and 30 controls). A no-cost extension was recently obtained in order to complete study in 2009. Data management activities, dietary data analysis, laboratory sample processing, and study data entry are currently underway. No final results from this study are yet available.

15. SUBJECT TERMS Prostate cancer, epidemiology, race, lifestyle risk factors

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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INTRODUCTION:

Prostate cancer has a huge and growing burden of disease, yet its natural history has not been fully elucidated. Further, it is unknown why African-American men have the highest incidence rates in the world. The ***overall goals of the ProCEED pilot study*** are: 1) to advance the understanding of the IGF axis and its interplay with race/genetics and dietary/lifestyle risk factors for prostate cancer, 2) To elucidate modifiable risk factors which interact with genetics and possibly lead to a greater incidence of prostate cancer among African-Americans, and 3) to disseminate learned information in an effort to prevent disease. It is hypothesized that racial differences in prostate cancer risk are attributed, in part, to interactions between lifestyle factors and the IGF axis. This study attempts to elucidate dietary and lifestyle risk factors which may operate/interact uniquely in African Americans. If there are lifestyle risk factors for prostate cancer which can be modified, this would be valuable information for primary and perhaps secondary prevention of prostate cancer.

BODY:

The third year of the grant was dedicated to continued subject enrollment. At the end of the enrollment period there were 87 subjects enrolled into the study (57 prostate cancer cases and 30 controls). A no-cost extension was recently obtained in order to complete study in 2009. Data management activities, dietary data analysis, laboratory sample processing, and study data entry are currently underway. No final results from this study are yet available.

PUBLICATIONS:

The third year of the grant was dedicated to continued subject enrollment in the clinic, and thus no new publications were submitted during the reporting period.

FUNDING:

There was no additional funding granted during the reporting period.

RESEARCH ACTIVITIES AND STATEMENT OF WORK:

Below is the approved statement of work with updates and changes described:

Task 1. Identification/recruitment subjects – Ongoing until month 30

As of the end of the reporting period there were 87 subjects enrolled (57 cases and 30 controls). Enrollment commenced in 2008 in order to focus on data management / analysis in 2009.

Task 2. Subject Recruitment and Data Collection, Months 2-29

When patients come in for a 60-minute study visit, the following tasks will take place:

i. Informed consent
ii. Demographic interview
iii. Waist/hip circumference and Height/weight measurement
iv. Blood sample
v. 24-hour dietary recall
vi. Work and social history questionnaire
vii. IPAQ exercise questionnaire
viii. Block Brief food frequency questionnaire
ix. Patient incentive given

In terms of data completeness at study completion, 100% of the subjects had: demographic interviews, height/weight measurements, blood samples, IPAQ exercise questionnaires, and work and social history questionnaires.

Dietary data is still coming in from the subjects (via USPS) but as of 12/29/08 there were 60 of 87 subjects that completed the Block Brief food frequency questionnaire, 57 of 87 subjects that completed at least one 24-hour food recall interview, and 42 of 87 that completed both of the 24-hour food recall interviews. We continue to follow-up with subjects to get as many questionnaires as possible in the final dataset.

Task 3. Determination of serum levels of IGF-1, IGFBP-3, PSA and testosterone, Months 2-29 (for collections and storage), Months 29-31 (for assays and data entry)

As enrollment is now completed, samples will be sent to the central laboratory for processing in mid-January, 2009. Results will be available for statistical analysis 2 weeks after the samples are shipped.

Task 4. Statistical Analyses, Months 30-36

Data is currently being data entered and cleaned. Statistical analysis will be done in mid-to-late January, 2009. A final dissertation report is due by August 2009 to the University of Illinois at Chicago Graduate College in order for Katrine Wallace to participate in the convocation.

KEY RESEARCH ACCOMPLISHMENTS:

- Enrolled 87 subjects into study, completed enrollment during reporting period

REPORTABLE OUTCOMES:

As the third year of the grant was dedicated to subject enrollment, there were no defined reportable outcomes during the reporting period. Manuscripts will be prepared in 2009 after the formal statistical analysis is completed.

CONCLUSIONS:

The third year of the grant was dedicated to continued subject enrollment. A no-cost extension was recently obtained in order to complete the data management / analysis in 2009. All results and conclusions will be contained in the 2009 report.